

PATENT

2 [2,6-dichlorophenyl)amino]benzene-acetic acid with a cyclic organic base as an active ingredient, said cyclic organic base comprising hydroxyethylpyrrolidine or hydroxyethylpiperidine, a pH adjuster and optionally, pharmaceutically acceptable thickening agents, humectants, fillers, preservatives and cross-linking agents to the steps of incorporating each ingredient, dissolving or dispersing a part or all of the ingredients in water, and kneading one ingredient with other ingredients while adjusting and maintaining a pH of the composition at a range of 7.3 to 9.0 during the step of preparation and then, spreading the resulting product over a support.

B1  
conceded.

48. An external anti-inflammatory and analgesic plaster comprising:

a preparation containing a salt of diclofenac, 2[(2,6-dichlorophenyl)amino]benzene-acetic acid with a cyclic organic base as an active ingredient, said cyclic organic base comprising hydroxyethylpyrrolidine or hydroxyethylpiperidine; a pH adjuster; pharmaceutically acceptable ingredients comprising a thickening agent; a humectant; a filler, a preservative and a cross-linking agent, wherein a pH value of the said preparation is adjusted to a range of 7.3 to 9.0; and a support on which said preparation is spread.

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REMARKS

This is responsive to the Office Action dated November 3, 1994.

In the Office Action, the Examiner rejected claims 1, 3 and 4 under 35 U.S.C. § 112, first paragraph. According to the Examiner, the disclosure is enabling only for claims limited to an external plaster preparation as described in

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claims 1, 3 and 4, wherein the cyclic organic base is defined as hydroxyethyl pyrrolidine or hydroxyethylpiperidine. Applicant has cancelled claims 1-4, and added new claims 5-8. In the new claims, the cyclic organic base is specified as hydroxyethyl pyrrolidine or hydroxyethylpiperidine. Accordingly, this rejection is now moot.

Claims 1-4 were also rejected under 35 U.S.C. § 112, second paragraph as being indefinite, due to the use of the phrases "general" and "such as." The Examiner suggested that the term "general" be deleted from the claims, and that the phrase "such as" be replaced with "comprising" at all occurrences in the claims. The Examiner also suggested that claim 1 be amended, penultimate line, by deleting "and also" and inserting "wherein." The suggestions provided by the Examiner have been utilized in drafting the new claims, and the objectionable phraseology has been omitted from these claims. Due to the more limited nature of the scope of the claims with regard to the cyclic organic base, the remaining grounds for the 35 U.S.C. § 112, second paragraph, rejection are moot.

The Examiner rejected claims 1-4 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103 as obvious over Ziggiotti, U.S. Patent 4,948,805. According to the Examiner, Ziggiotti discloses a preparation comprising diclofenac salt with a cyclic organic base, which base is hydroxyethylpyrrolidine. The Examiner noted that Ziggiotti does not disclose an external plaster.

Applicant respectfully submits that the present claims are neither anticipated by, nor obvious over the Ziggiotti patent. Ziggiotti discloses pharmaceutical compositions

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containing a salt of diclofenac with hydroxyethylpyrrolidine, which is soluble in water to form a solution suitable for oral administration.

However, Ziggiotti does not disclose that such a salt can be used as a pharmaceutically effective component of an external anti-inflammatory and analgesic plaster preparation. That is, the present invention is directed to an external anti-inflammatory and analgesic plaster to be applied on the skin of the human body. For this, the present plaster includes optionally pharmaceutically acceptable thickening agents, humectants, fillers, preservatives and cross-linking agents. Therefore, the present invention includes ingredients not taught in Ziggiotti, and belongs to a different field of art when compared to Ziggiotti.

One of the unexpected effects of the present invention resides in that the pharmaceutical effect is kept for a long period of time after applied to the human body. This is because the pH adjuster maintains the desirable pH value for suitably controlling release of the salt. The graph attached shows the test results of the changes of the plasma concentration of diclofenac with lapse of time, from which it can be seen that the effect is kept for a long time. In addition, the optionally added cross-linking agent acts to cross-link the water-soluble and ionic polymers, thereby to prevent that part of the plaster that might be left on the skin when being stripped off. Such effects are not disclosed in Ziggiotti.

The Examiner has pointed out that the present claims lack definition of the plaster or support. New claim 8 specifically includes such a support.

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Based upon the foregoing, Applicant respectfully requests that the grounds for rejection have been overcome, and that all claims 5-8 are in condition for allowance. Accordingly, Applicant respectfully requests the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution of this matter could be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,

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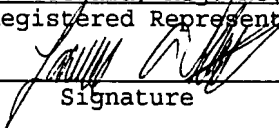
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on: March 30, 1995.

Lawrence A. Steward, Reg. No. 32,309  
Name of Registered Representative

  
Signature

March 30, 1995  
Date

Treatment A : placebo  
Treatment B : gel

Mean values (n = 10)

Plasma concentrations of Diclofenac as ng/ml.

